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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	INT 004.10	8022

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/31/07, 6/4/07, 6/7/07 and 7/19/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/31, 6/4, 6/7 and 7/19*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/31/2007 has been entered. An action on the RCE follows.

2. Claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47 and 68-85 have been cancelled. Claims 86-88 have been amended. Claims 89-113 have been added.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

4. Applicant has amended the title to better reflect the invention.

5. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response (including amendments) and withdrawn.

Information Disclosure Statement

6. The information disclosure statements submitted on 5/31/2007, 6/4/2007, 6/7/2004 and 7/19/2007 have been fully considered.

Specification

7. The disclosure is objected to because of the following informalities: The amendments to the description of Figure 2 appear to be new matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8a. Claims 86-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966).

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject. The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via a device such as an implanted pump.

Parker *et al* teaches treatment of viral diseases by administering an omega IFN-expressing polynucleotide (see page 5, lines 12-21), and specifically HCV (page 3, lines 24-25; page 23, lines 14-28; Example 6). The reference demonstrates that administration of an omega IFN-expressing polynucleotide is capable of increasing serum omega IFN levels in a subject, and that this increased serum omega IFN can be beneficial in the treatment of HCV. Furthermore, Parker *et al* teaches treatment of HCV by administration of an omega IFN-expression polynucleotide (see claims 1 and 29).

Parker *et al* is silent regarding administration of omega IFN protein or use of any device for administration.

Goeddel *et al* teaches an interferon, termed "leukocyte interferon", or IFN-□$_{II}$1, which the instant specification discloses to be omega IFN (paragraph 0053 of instant specification). Goeddel *et al* teaches that this IFN possess biological activities similar or overlapping with other type I IFNs, including antiviral activity (column 2, line 67 – column 3, line 4; column 7, line 50 – column 8, line 19), and is suitable for therapeutic applications for treatment of viral infections and malignant and immunosuppressed or immunodeficient conditions (column 3, lines 15-19). However, Goeddel *et al* does not specifically teach administration of omega IFN for treatment of HCV infection.

Theeuwes *et al* discloses an implantable, osmotic pump suitable for long-term administration of various drugs (abstract, column 2, line 53 – column 4, line 14), but is silent regarding a method of treatment of HCV by administration of omega IFN, or use of an implantable, osmotic pump in said method.

However, one of ordinary skill in the art, at the time the instant invention was conceived, would have been motivated to practice the method of the instant invention by following the combined teachings of Parker *et al*, Goeddel *et al*, and Theeuwes *et al*. The disclosure of Parker *et al*, by teaching that HCV infection can be treated by omega IFN expressed in a subject by administration of a polynucleotide encoding omega IFN, provides the motivation to treat HCV by administration of omega IFN protein. Goeddel *et al*, by teaching that omega IFN protein possesses type I IFN biological activity,

including antiviral activity, provides further motivation to use omega IFN, and also provides the skilled artisan with the knowledge of a specific omega IFN polypeptide.

Furthermore, because Parker *et al* suggests that therapeutic, systemic levels of omega IFN are beneficial for treatment of viral infections such as HCV (page 24, lines 23-38), one of ordinary skill in the art would be motivated to practice a method of omega IFN administration that results in sustained levels of omega IFN. Theeuwes *et al*, by teaching an implantable osmotic pump capable of long-term delivery of pharmaceutical agents, provides a device capable of sustained delivery of omega IFN. Therefore, the combined teachings of Parker *et al*, Goeddel *et al*, and Theeuwes *et al* provides a person of ordinary skill in the art with the motivation to treat HCV infection by sustained administration of the omega IFN of Goeddel *et al*, via the implantable osmotic pump of Theeuwes *et al.*

Finally, although the combination of Parker *et al*, Goeddel *et al*, and Theeuwes *et al* does not specifically recite the claimed dosages, timing of administration, or routes of administration, a person of ordinary skill in the art would have both the motivation and the ability to optimize these variables to practice the most effective method of treatment. MPEP 2144.05 states:

> "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 454, 105 USPQ 223, 235, (CCPA 1955).

In the instant case, the general conditions of the claims, administration of omega IFN for treatment of HCV infection, are obvious in view of the combination of Parker *et al*, Goeddel *et al*, and Theeuwes *et al*, and therefore it would be obvious to optimize conditions such as dosage and timing and route of administration.

8b. Claims 86, 97, 103 and 109-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al* (US 6,074,673).

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject. The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via a device such as an implanted pump. The claims are also drawn to a kit comprising the device.

The teachings of Parker *et al*, Goeddel *et al* and Theeuwes *et al*, have been disclosed above in paragraph 5a. However, these teachings do not disclose kit with multiple implantable devices.

Guillen discloses kit with multiple implantable devices with different concentration of medication (column 3, lines 55-65). It also discloses slow release of the medicament (column 3, lines 55-65). The reference is silent regarding a method of treatment of HCV by administration of omega IFN, or use of an implantable, osmotic pump in said method.

It would have been *prima facie* obvious to the artisan of ordinary skill in the art to modify the methods disclosed in the Parker *et al*, Goeddel *et al* and Theeuwes *et al* to also contain a kit disclosed in Guillen to contain multiple implants for the administration of interferon-omega to treat HCV. Then artisan would have been motivated to include a kit with multiple implantable devices to generate varied doses because this will allow the subject to maintain the desired levels of interferon-omega during extended periods for the treatment of HCV. There is a reasonable expectation of success because Guillen discloses use of these kits with multiple implantable devices for allergy desensitization. Therefore, claims 86, 97, 103 and 109-113 are rejected as being obvious over the combined teaching of Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al* (US 6,074,673).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9a. Claims 86-108 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65 and 86-104 of copending Application No. 10/982,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention and that of '532 are both directed to method of treating HCV by administering IFN-omega. The patient population that is treated in the instant invention will also encompass the patient population of '532 Application that is resistant ton alpha interferon. Therefore, claims 86-108 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 65 and 86-104 of copending Application No. 10/982,532.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner.

JS
Art Unit 1647,
August 22nd, 2007